ZIMMER® spine

510(k) SUMMARY

TiTLE® 2 Polyaxial Spinal System

Date of Summary Preparation: *27 September 2013*

Submitter:
Zimmer Spine, Inc.
7375 Bush Lake Road
Minneapolis, MN 55439

NOV 2 7 2013

Establishment Registration Number: 2184052 (Minneapolis)

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Trade Name: *TiTLE® 2 Polyaxial Spinal System*

Device Name (Common Name): Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease; Orthosis, Spondylolisthesis Spinal Fixation; Orthosis, Spinal Pedicle Fixation; Appliance Fixation, Spinal Interlaminal/Spinal interlaminal fixation Orthosis

Device Classification: Class III

Product Code(s): NKB, MNH, MNI, KWP

Regulation Numbers:
21 CFR § 888.3070
21 CFR § 888.3050

Regulation Description: Pedicle screw spinal system

Predicate Devices:
The subject *TiTLE® 2 Polyaxial Spinal System* claims to be substantially equivalent to the following legally marketed predicate devices:

TiTLE® 2 Polyaxial Spinal System Predicate Device Name	Submission ID Number	Clearance Date
TiTLE® 2 Polyaxial Spinal System	K073510	February 11, 2008
TiTLE® 2 Polyaxial Spinal System	K072840	December 7, 2007
TiTLE® 2 Polyaxial Spinal System	K070367	April 12, 2007
TiTLE® 2 Polyaxial Spinal System	K060990	April 26, 2006
TiTLE® 2 Polyaxial Spinal System	K041808	October 1, 2004

General Device Description:

The *TiTLE® 2 Polyaxial Spinal System* Implants are intended to be used as a temporary construct that assists in normal healing and are not intended to replace normal body structures. The system is intended to stabilize the spinal operative site during posterior fusion procedures, attaching to the spine by means of screws joined with spinal rods and should be removed after fusion.

The *TiTLE® 2 Polyaxial Spinal System* is designed to aid in the surgical correction of several types of spinal conditions, as stated in the section below. The *TiTLE® 2 Polyaxial Spinal System* consists of screws, rods, connection components that are intended to be used as a temporary construct that assists in normal healing and are not intended to replace normal body structures. The system is intended to stabilize the spinal operative site during posterior fusion procedures, attaching to the spine by means of screws joined with spinal rods and should be removed after fusion. The polyaxial spinal system is a rod and top-loading screw fixation system. This system can be placed surgically using either open or endoscopic surgical techniques. The system is provided non-sterile, for single use only.

The *TiTLE® 2 Polyaxial Spinal System* can also be linked to the Minit® Posterior Cervical and Upper Thoracic Fixation System.

Indications for Use:

The *TiTLE 2 Polyaxial Spinal System* is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the Thoracic, Lumbar and Sacral spine.

The *TiTLE 2 Polyaxial Spinal System* is a Pedicle Screw System intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The *TiTLE 2 Polyaxial Spinal System* is also indicated for pedicle screw fixation for severe spondylolisthesis (grades 3 and 4) at L5-S1, in skeletally mature patients, when autogenous bone graft is used, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is attained. Levels of fixation are from L3-S1.

In addition, *TiTLE 2 Polyaxial Spinal System*, when not used with pedicle screws, is indicated for sacral screw fixation from T1 to the ilium sacrum. The non-pedicle screw indications are spondylolisthesis, degenerative disc disease, (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis, and kyphosis), tumor, fracture, and previous failed fusion surgery.

The *TiTLE 2 Polyaxial Spinal System* can also be linked to the Minit® Posterior Cervical and Upper Thoracic Fixation System.

Summary of Technological Characteristics:

The subject *TiTLE® 2 Polyaxial Spinal System* shares the same technological characteristics as its predicate device, TiTLE® 2 Polyaxial Spinal System. The characteristics include the same design, same materials, same range of sizes and, substantially equivalent performance characteristics and intended use.

The subject and predicate *TiTLE® 2 Polyaxial Spinal System* both consist of screws, rods, connection components and the instruments necessary to implant the spinal system. All implant components are made from medical grade titanium or titanium alloy (Ti-6Al-4V ELI) that meets ASTM F136. The delivery instruments are manufactured from Stainless Steel that meets ASTM A564 and ASTM F899.

The *TiTLE® 2 Polyaxial Spinal System* is designed to aid in the surgical correction of several types of spinal conditions, as stated in the section above. The *TiTLE® 2 Polyaxial Spinal System* consists of screws, rods, connection components that are intended to be used as a temporary construct that assists in normal healing and are not intended to replace normal body structures. The system is intended to stabilize the spinal operative site during posterior fusion procedures, attaching to the spine by means of screws joined with spinal rods and should be removed after fusion. The polyaxial spinal system is a rod and top-loading screw fixation system. This system can be placed surgically using either open or endoscopic surgical techniques. The subject and predicate systems are provided non-sterile, are for single use only.

Summary of Performance Testing:

The *TiTLE® 2 Polyaxial Spinal System* is substantially equivalent to the predicate devices in design, materials, function and intended use.

The performance testing included components of the subject *TiTLE® 2 Polyaxial Spinal System*, which were reviewed and tested appropriately for design verification, design validation, biocompatibility and sterilization. The test results conclude the subject *TiTLE® 2 Polyaxial Spinal System* to be substantially equivalent to its predicate device, TiTLE® 2 Polyaxial Spinal System.

- Bench testing (Static Axial Compression (Bending), Static Torsion, and Axial Compression (Bending) Fatigue per ASTM F1717-12; and Static Axial Gripping Capacity, Static Torsion Gripping Capacity, Static Flexion-Extension Moment, and Dynamic Flexion-Extension Moment per ASTM F1798-97 (Reapproved 2008)) for implants, screws, rods, and connection component, confirmed the product performance of the subject *TiTLE® 2 Polyaxial Spinal System* is suitable for its intended use.
- Cadaver lab testing of the subject *TiTLE® 2 Polyaxial Spinal System* to evaluate human factors regarding the combination of instrument design changes and labeling design changes, as well as interaction with implants to confirm the substantial equivalence of the changes compared to the identified predicate devices.
- Biocompatibility testing ensured the subject *TiTLE® 2 Polyaxial Spinal System* materials are biocompatible after manufacturing based on the minor design changes made in comparison to the predicate devices.
- Sterilization, and Dry Time testing ensured the subject *TiTLE® 2 Polyaxial Spinal System* steam sterilization, and dry time requirements and instructions are substantially equivalent to the predicate devices.

Substantial Equivalence:

Zimmer Spine considers the subject *TiTLE® 2 Polyaxial Spinal System* product performance to be substantially equivalent to its predicate device, *TiTLE® 2 Polyaxial Spinal System* because there are no changes to the product performance specifications or device functional scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Zimmer Spine, Incorporated
Ms. Michelle Lenz
Regulatory Affairs Specialist
7375 Bush Lake Road
Minneapolis, Minnesota 55439

November 27, 2013

Re: K133086
Trade/Device Name: TiTLE® 2 Polyaxial Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWP
Dated: September 27, 2013
Received: September 30, 2013

Dear Ms. Lenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133086

Device Name: *TiTLE® 2 Polyaxial Spinal System*

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Prescription Use ____X____ AND/OR Over-the Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133086